

REMARKS

This application is a continuation-in-part of U.S. Application Serial No. 09/728,540, filed November 28, 2000, now abandoned; which claims priority from both U.S. Provisional Application Serial No. 60/207,558 and is a continuation-in-part of copending U.S. Application Serial No. 09/073,363, filed May 6, 1998, now abandoned; which claims priority from U.S. Provisional Application Serial Nos. 60/044,293, 60/076,947 and 60/072,212; all of which are incorporated herein by reference.

Claims 1 and 23-26 will be pending after entry of this Amendment and Response. Claims 2-7 and 9-22 have been withdrawn from consideration by the Examiner. Claims 1 and 8 stand rejected. Claim 1 has been amended. Claims 2-22 have been canceled. Claims 23-26 have been added.

New Claims

New claims 23-26 have been added. Support for the new claims can be found, for example, in applicants' published U.S. application (Publication No. US 2003/0032090) in paragraphs 74-77. Accordingly, no new matter has been added.

Objection to the Information Disclosure

The Examiner stated that references AE, AQ, AR, AS, AT, AU, AV, AW, AX, AZ, BD, BE, BF, BI, BJ, BK, BL, BN, BP and BR, which applicants cited in its Information Disclosure Statement, were not considered because the relevance of the references was not clear. The Examiner asked applicants to indicate the relevance of the above references to the claimed invention.

The application, as filed, contained claims directed to TLRs 2-10. Each of the references cited in applicants' Information Disclosure Statement relates to one or more of

TLRs 2-10. However, not every cited reference relates to each individual TLR. Applicants point out that the Information Disclosure Statement was submitted before the Examiner's requirement for restriction.

Applicants respectfully request that each of the above references be considered by the Office. According to 37 C.F.R. § 1.97, Information Disclosure Statements shall be considered by the Office. In addition, under 37 C.F.R. §1.98, applicants are required to provide a concise explanation of the relevance of a reference only if the reference is not in the English language. Therefore, it is applicants' understanding that all references submitted in the English language in an Information Disclosure Statement shall be considered by the Office. If the Examiner is still unwilling to consider the above references, the Examiner is asked to contact the undersigned to discuss this matter further.

Objection to the Specification

The Examiner has objected to the specification, indicating that it should be arranged in a preferred format. Applicants have amended the specification according to the Examiner's suggestion. Accordingly, withdrawal of the objection to the specification is respectfully requested.

Claim Objection

Claim 1 is objected to for reciting non-elected SEQ ID NOs. Applicants have amended claim 1 so that it only recites previously elected SEQ ID NO: 12. Accordingly, withdrawal of the objection to claim 1 is respectfully requested.

Rejection under 35 U.S.C. §§ 101/112, first paragraph

Claims 1 and 8 stand rejected under 35 U.S.C. § 101 as lacking utility. Specifically, the Examiner stated that the claims lack a specific and substantial utility or a well established utility. In addition, Claims 1 and 8 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Specifically, the Examiner stated that the claimed invention is not supported by either a substantial asserted utility or a well established utility so one of skill in the art would not know how to use the claimed invention.

Claim 8 has been canceled so the rejection under 35 U.S.C. § 101/112, first paragraph with respect to that claim is moot. However, applicants submit that claim 1 and new claims 23-26 are patentable under 35 U.S.C. §§ 101 and 112, first paragraph.

Applicants' specification and claims are directed to DNAX TLR6, which is strictly applicants' nomenclature. Applicants' DNAX TLR6 corresponds to TLR7 in the public nomenclature.

Applicants' specification ascribes several biological functions to TLRs. Please see, for example, paragraphs 2, 78, 83 and 190 of the published U.S. application, U.S. Publication No. 2003/0032090. Furthermore, paragraph 187 of applicants' specification clearly asserts that oligonucleotide or polynucleotide sequences derived from TLRs would be useful in the diagnosis of immunological disorders. The veracity of this asserted utility is evidenced by the Declaration of Terrill McClanahan (filed concurrently herewith).

Specifically, the McClanahan Declaration demonstrates that nucleotide probes derived from TLR7 DNA sequences may be used to diagnose immunological disorders such as psoriasis and atopic dermatitis (see paragraphs 5-7 of the Declaration). The experiments referred to in the McClanahan Declaration examined TLR7 mRNA expression levels in psoriasis and atopic dermatitis skin samples and compared them to TLR7 mRNA levels in normal skin samples. The data show that diseased tissues had higher levels of TLR7 mRNA

than normal tissues. Thus, the data confirms the usefulness of TLR7 nucleotide sequences in the diagnosis of immunological disorders, such as psoriasis and atopic dermatitis.

One of skill in the art would expect the increase in TLR7 mRNA levels to correlate with increased TLR7 protein expression. Therefore, the claimed polypeptides would be useful, for example, to generate antibodies, which could be used in the diagnosis of psoriasis and atopic dermatitis. Alternatively, the claimed polypeptides may also be used to generate oligonucleotide probes for use in the diagnosis of psoriasis and atopic dermatitis.

In conclusion, applicants submit that claim 1 and new claims 23-26 satisfy the requirements of 35 U.S.C. § 101/112, first paragraph, as the claimed polypeptides have a specific and substantial asserted utility and one of skill in the art would know how to use the claimed invention. Accordingly, withdrawal of the rejection under 35 U.S.C. § 101/112, first paragraph is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

Written Description

Claims 1 and 8 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. Specifically, the Examiner stated that an allelic variant of SEQ ID NO: 12 or an antigenic fragment thereof are not described in such a way as to reasonably convey to one of skill in the art that the inventor had possession of the claimed invention.

Claim 1 has been amended to delete the phrase "an antigenic fragment thereof". Claim 8 has been canceled. Therefore, applicants submit that the rejection under 35 U.S.C. § 112, first paragraph, for lack of written description with respect to those claims is moot.

In addition, applicants submit that new claims 23-26 satisfy the written description requirements of 35 U.S.C. § 112, first paragraph. New claims 23-26 are directed to isolated or recombinant polypeptides that exhibit sequence identity over a length of at least 10 (claim

23), 16 (claim 24), 22 (claim 25) or 28 (claim 26) amino acids to SEQ ID NO: 12.

Accordingly, the structural features of the claimed polypeptides are clearly recited and one of skill in the art would recognize that applicants were in possession of the claimed invention.

In conclusion, applicants submit that claim 1 and new claims 23-26 satisfy the requirements of 35 U.S.C. § 112, first paragraph.

Withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner stated that the recitation of "The isolated" should be amended to recite "An isolated". Claim 1 has been amended according to the Examiner's suggestion.

Withdrawal of the rejection of claim 1 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claim 8 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 8 has been canceled. Withdrawal of the rejection of claim 8 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

CONCLUSION

Applicants submit that claims 1 and 23-26 are described in the specification. In addition, applicants submit that the subject matter of claims 1 and 23-26 are useful. Accordingly, reconsideration of the rejections and allowance of the claim at an early date are earnestly solicited.

If the undersigned can be of assistance to the Examiner in addressing issues to advance the application to allowance, please contact the undersigned at the number set forth below.

Respectfully submitted,



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